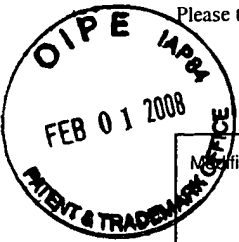


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Modified Form 1449/PTO				Application Number		10/532,293	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Filing Date		February 17, 2006	
				First Named Inventor		Brand	
				Group Art Unit		1647	
				Examiner Name		Elly Gerald Stoica	
				Attorney Docket Number		24492-011 NATL	
U.S. PATENT DOCUMENTS							
Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate
	*A38	6,558,952 B1	05/06/03	Parikh et al.	435	384	
	*A39	5,120,712	06/09/92	Habener	514	12	
	*A40	5,158,935	10/27/92	Nascimento et al.	514	12	
	*A41	5,362,716	11/08/94	Kmiecik et al.	514	12	
	*A42	5,424,286	06/13/95	Eng	514	2	
	*A43	5,512,549	04/30/96	Chen et al.	514	12	
	*A44	5,545,618	08/13/96	Buckley et al.	514	12	
	*A45	5,587,309	12/24/96	Rubin et al.	435	240.2	
	*A46	5,863,555	01/26/99	Heiber et al.	424	435	
	*A47	5,977,071	11/02/99	Galloway et al.	514	12	
	*A48	6,011,155	01/04/00	Villhauer	544	333	
	*A49	6,133,235	10/17/00	Galloway et al.	514	12	
	*A50	6,162,907	12/19/00	Habener	536	23.1	
	*A51	6,191,102 B1	02/20/01	DiMarchi et al.	514	2	
	*A52	6,268,343 B1	07/31/01	Knudsen et al.	514	12	
	*A53	6,451,974 B1	09/17/02	Hansen	530	345	
	*A54	6,458,764 B1	10/01/02	Gravel et al.	514	12	
	*A55	6,458,924 B2	10/01/02	Knudsen et al.	530	324	
	*A56	6,506,724 B1	01/14/03	Hiles et al.	514	2	
	*A57	6,514,500 B1	02/04/03	Bridon et al.	424	193.1	
	*A58	6,858,576 B1	02/22/05	Young et al.	514	2	
	*A59	6,872,700 B1	03/29/05	Young et al.	514	2	
	*A60	6,902,744 B1	06/07/05	Kolterman et al.	424	489	
	*A61	6,956,026 B2	10/18/05	Beeley et al.	514	12	
	*A62	7,202,080 B2	04/10/07	Ramiya et al.	435	325	
	*A63	7,211,557 B2	05/01/07	DiMarchi et al.	514	2	

U.S. PUBLISHED APPLICATION DOCUMENTS							
Exam Initials	Cite No.	U.S. Published Application No.	Published Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate
	*A64	01/0006943 A1	07/05/01	Jensen et al.	514	12	
FOREIGN PATENT DOCUMENTS							
Exam Initials	Cite No.	Foreign Patent Document Office Number	Name of Patentee(s) or Applicant(s)		Date of Publication	Translation Yes No	
	B20	EP 0 619 322 B1	SCIOS, INC.		10/12/94		
	B21	EP 0 699 686 B1	ELI LILLY & CO.		03/06/96		
	B22	EP 0 708 179 B1	ELI LILLY & CO.		04/24/96		
	B23	EP 0 869 135 A1	ELI LILLY & CO.		10/07/98		
	B24	WO 87/06941	GENERAL HOSPITAL CORPORATION		11/19/87		
	B25	WO 90/05185	L'UNIVERSITE DE L'ETATE A LIEGE		05/17/90		
	B26	WO 90/11296	GENERAL HOSPITAL CORPORATION		10/04/90		
	B27	WO 91/11457	BUCKLEY ET AL.		08/08/91		
	B28	WO 93/18786	NOVO NORDISK		09/30/93		
	B29	WO 93/19175	NOVO NORDISK		09/30/93		
	B30	WO 93/25579	PFIZER INC.		12/23/93		
	B31	WO 95/31214	LONDON HEALTH ASSOCIATION		11/23/95		
	B32	WO 97/40832	HANS-KNOLL INSTITUTE		11/06/97	Abstract Only	
	B33	WO 98/08871	NOVO NORDISK		03/05/98		
	B34	WO 99/38501	TUFTS COLLEGE		08/05/99		
	B35	WO 99/43341	NOVO NORDISK		09/02/99		
	B36	WO 99/43705	NOVO NORDISK		09/02/99		
	B37	WO 99/43706	NOVO NORDISK		09/02/99		
	B38	WO 99/43707	NOVO NORDISK		09/02/99		
	B39	WO 99/43708	NOVO NORDISK		09/02/99		
	B40	WO 99/46272	FONDATECH BENELUX		09/16/99		
	B41	WO 99/61431	PROBIODRUG		12/02/99	Abstract Only	
	B42	WO 99/67278	PROBIODRUG		12/29/99	Abstract Only	
	B43	WO 99/67279	PROBIODRUG		12/29/99	Abstract Only	
	B44	WO 00/07617	NOVO NORDISK		02/17/00		
	B45	WO 00/42026	NOVO NORDISK		07/20/00		
	B46	WO 00/66629	AMYLIN PHARMACEUTICALS, INC.		11/09/00		
	B47	WO 01/04156 A1	ZEALAND PHARMACEUTICALS		01/18/01		
	B48	WO 01/98331 A2	ELI & LILLY & CO.		12/27/01		
	B49	WO 02/012452 A2	CURIS INC.		02/14/02		
	B50	WO 2007/041833 A1	WARATAH PHARMACEUTICALS		04/19/07		
	B51	WO 2007/062531 A1	WARATAH PHARMACEUTICALS		06/07/07		
	B52	WO 2007/095737 A1	WARATAH PHARMACEUTICALS		08/30/07		

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
	C131	Abe et al., "First Synthesis and Determination of the Absolute Configuration of Sulphostin, a Novel Inhibitor of Dipeptidyl Peptidase IV", <i>J Nat Prod</i> , 67:999-1004 (2004)
	C132	Ahmed et al., "High and Low Affinity Receptors Mediate Growth Effects of Gastrin and Gastrin-Gly on DLD-1 Human Colonic Carcinoma Cells", <i>FEBS Letters</i> , 556:199-203 (2004)
	C133	Ahren B., "Beta-Cell expression of a dominant-negative HNF-1 α compromises the ability of inhibition of dipeptidyl peptidase-4 to elicit a long-term augmentation of insulin secreted in mice", <i>Euro J of Pharmacology</i> , 521:164-168 (2005)
	C134	Ahren et al., "Inhibition of Dipeptidyl Peptidase IV Improves Metabolic Control Over a 4-Week Study Period in Type 2 Diabetes", <i>Diabetes Care</i> , 25:869-875 (2002)
	C135	Ahren et al., "Inhibition of Dipeptidyl Peptidase-4 Reduces Glycemia, Sustains Insulin Levels, and Reduces Glucagon Levels in Type 2 Diabetes", <i>J Clin Endocrinol Metab</i> , 89:2078-2084 (2004)
	C136	Baggio et al., "Therapeutic approaches to preserve islet mass in type 2 diabetes", <i>Annual Review of Medicine</i> , 57:265-281 (2006)
	C137	Bonner-Weir et al., "In vitro cultivation of human islets from expanded ductal tissue", <i>PNAS</i> , 97(14): 7999-8004 (2000)
	C138	Brand et al., "Prolonged Efficacy of Islet Neogenesis Therapy with Gastrin and TGF α in Mature Rats with Preexisting Diabetes", <i>Diabetes</i> , 50(Suppl 2):A338 (Abstract) (2001)
	C139	Caldwell et al., "Fluoropyrrolidine amides as dipeptidyl peptidase IV inhibitors", <i>Bioorg Med Chem Lett</i> , 14:1265-1268 (2004)
	C140	Chatenoud, L., "Restoration of Self-Tolerance Is a Feasible Approach to Control Ongoing Beta-Cell Specific Autoreactivity: Its Relevance for Treatment in Established Diabetes and Islet Transplantation", <i>Diabetologia</i> , 44:521-536 (2001)
	C141	Chatenoud et al., "Anti-CD3 Antibody Induces Long-Term Remission of Overt Autoimmunity in Nonobese Diabetic Mice", <i>Proc Natl Acad Sci U S A</i> , 91:123-127 (1994)
	C142	Chepurny et al., "Over-expression of the glucagon-like peptide-1 receptor on INS-1 cells confers autocrine stimulation of insulin gene promoter activity: a strategy for production of pancreatic β -cell lines for use in transplantation", <i>Cell & Tissue Research</i> , 307(2):191-201 (2002)
	C143	Chou et al., "A Radioimmunoassay for LY315902, an Analog of Glucagon-Like Insulinotropic Peptide, and Its Application in the Study of Canine Pharmacokinetics", <i>J Pharm Sci</i> , 86(7):768-773 (1997)
	C144	Deacon et al., "Dipeptidyl Peptidase IV Inhibition Potentiates the Insulinotropic Effect of Glucagon-Like Peptide 1 in the Anesthetized Pig", <i>Diabetes</i> , 47:764-769 (1998)
	C145	Drucker, D.J., "Glucagon-Like Peptides: Regulators of Cell Proliferation, Differentiation, and Apoptosis", <i>Molecular Endocrinology</i> , 17(2):161-171 (2003)
	C146	Edmondson et al., "Potent and selective proline derived dipeptidyl peptidase IV inhibitors", <i>Bioorg Med Chem Lett</i> , 14:5151-5155 (2004)
	C147	Garcia-Ocana et al., "Transgenic Overexpression of Hepatocyte Growth Factor in the Beta-Cell Markedly Improves Islet Function and Islet Transplant Outcomes in Mice", <i>Diabetes</i> , 50:2752-2762 (2001)
	C148	Gmyr et al., "Adult human cytokeratin 19-positive cells reexpress insulin promoter factor 1 in vitro: Further evidence for pluripotent pancreatic stem cells in humans", <i>Diabetes</i> , 49(10):1671-80 (2000)
	C149	Holst, "Therapy of type 2 diabetes mellitus based on the actions of glucagon-like peptide-1", <i>Diabetes Metab Res Rev</i> , 18:430-441 (2002)
	C150	Kieffer Tjet et al., "Degradation of Glucose-Dependent Insulinotropic Polypeptide and Truncated Glucagon-Like Peptide 1 in Vitro and in Vivo by Dipeptidyl Peptidase IV", <i>Endocrinology</i> , 136(8):3585-3596 (1995)

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
	C151	Korc, "Islet Growth Factors: Curing Diabetes and Preventing Chronic Pancreatitis?", <i>Clin. Invest.</i> , 92:1113-1114 (1993)
	C152	Lankas et al., "Dipeptidyl peptidase IV inhibition for the treatment of type 2 diabetes: potential importance of selectivity over dipeptidyl peptidases 8 and 9", <i>Diabetes</i> , 54:2988-2994 (2005)
	C153	Lefebvre et al., "Culture of Adult Human Islet Preparations With Hepatocyte Growth Factor and 804G Matrix Is Mitogenic for Duct Cells but Not for Beta-Cells", <i>Diabetes</i> , 47:134-137 (1998)
	C154	McIntosh et al., "Applications of Dipeptidyl-Peptidase IV Inhibitors in Diabetes Mellitus", <i>Int J of Biochemistry & Cell Biology</i> , 38:860-872 (2006)
	C155	Mentlein et al., "Dipeptidyl-Peptidase IV Hydrolyses Gastric Inhibitory Polypeptide, Glucagon-Like Peptide-1(7-36)Amide, Peptide Histidine Methionine and Is Responsible for Their Degradation in Human Serum", <i>Eur J Biochem</i> , 214:829-835 (1993)
	C156	Moller, "New Drug Targets for Type 2 Diabetes and the Metabolic Syndrome", <i>Nature</i> , 414:821-827 (2001)
	C157	Nauck, "Glucagon-like peptide 1 (GLP-1): a potent gut hormone with a possible therapeutic perspective", <i>Acta Diabetol</i> , 35:117-129 (1998)
	C158	Otonkoski et al., "Nicotinamide and Sodium Butyrate Have Potent Synergistic Effects on Fetal Porcine β -Cell Proliferation", <i>Diabetologia</i> , 39(Supple 1):Abstract 232 (1996)
	C159	Patel et al., "Treatment of non-insulin-dependent diabetes mellitus", <i>Expert Opinion Investig Drugs</i> , 12(4):623-33 (2003)
	C160	Pederson et al., "Improved Glucose Tolerance in Zucker Fatty Rats by Oral Administration of the Dipeptidyl Peptidase IV Inhibitor Isoleucine Thiazolidide", <i>Diabetes</i> , 47:1253-1258 (1998)
	C161	Peters et al., "Aminomethylpyridines as DPP-IV inhibitors", <i>Bioorg Med Chem Lett</i> , 14:3579-3580 (2004)
	C162	Sandgren et al., "Overexpression of TGF α in Transgenic Mice: Induction of Epithelial Hyperplasia, pancreatic Metaplasia and Carcinoma of the Breast", <i>Cell</i> , 61:1121-1135 (1990)
	C163	Sasaki et al., "Successful Long-Term Kidney-Pancreas Transplants in Diabetic Patients with High C-Peptide Levels", <i>Transplantation</i> , 65(11):1510-1512
	C164	Sharp et al., "Transforming growth factor alpha disrupts the normal program of cellular differentiation in the gastric mucosa of transgenic mice", <i>Development</i> , 121:149-161 (1995)
	C165	Sjoholm, "Diabetes mellitus and Impaired Pancreatic Beta-cell proliferation", <i>Journal of Internal Medicine</i> , 239(3):211-220 (1996)
	C166	Stoffers et al., "Early-Onset Type-II Diabetes Mellitus (MODY4) Linked to IPF1", <i>Nat Genet</i> , 17:138-139 (1997)
	C167	"Transition Therapeutics Confirms Effectiveness of Islet Neogenesis Therapy in Reducing Diabetic Symptoms", Transition Therapeutics Press Release, April 17, 2002
	C168	"Transition Therapeutics Inc. Receives Approval to Initiate Phase I Clinical Trial for Islet Neogenesis Therapy", Transition Therapeutics Press Release, September 20, 2002
	C169	"Transition Therapeutics' I.N.T. TM Treatment Stimulates Regeneration of Human Insulin-Producing Cells", Transition Therapeutics Press Release, September 26, 2002
	C170	"Transition Therapeutics' I.N.T. TM Treatment Increases Survival", Transition Therapeutics Press Release, September 27, 2002
	C171	Veves et al., "Can VEGF Reverse Diabetic Neuropathy in Human Subjects?", <i>J Clin Invest</i> , 107(10):1215-1218 (2001)
	C172	Villhauer et al., "1-[2-[(5-Cyanopyridin-2-yl)amino]ethylamino]acetyl-2-(S)-pyrrolidinecarbonitrile: a potent, selective, and orally bioavailable dipeptidyl peptidase IV inhibitor with antihyperglycemic properties", <i>J Med Chem</i> , 45:2362-2365 (2002)

Express Mail No.: EV 871033984 US
Date of Deposit: February 1, 2008

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Attorney Docket No.: 24492-011 NATL

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
	C173	Villhauer et al., "1-[[[3-hydroxy-1-adamantyl)amino]acetyl]-2-cyano-(S)-pyrrolidine: a potent, selective, and orally bioavailable dipeptidyl peptidase IV inhibitor with antihyperglycemic properties", <i>J Med Chem</i> , 46:2774-2789 (2003)
	C174	Von Herrath, "E1-INT Transition Therapeutics/Novo Nordisk", <i>Current Opinion Investig Drugs</i> , 6(10):1037-1042 (2005)

* By the waiver of 37 CFR 1.98(a)(2)(ii) copies of the U.S. Patents A38-A63 and U.S. Published Application A64 are not submitted.

Examiner Signature		Date Considered	
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